Quality Procedure

Design Management

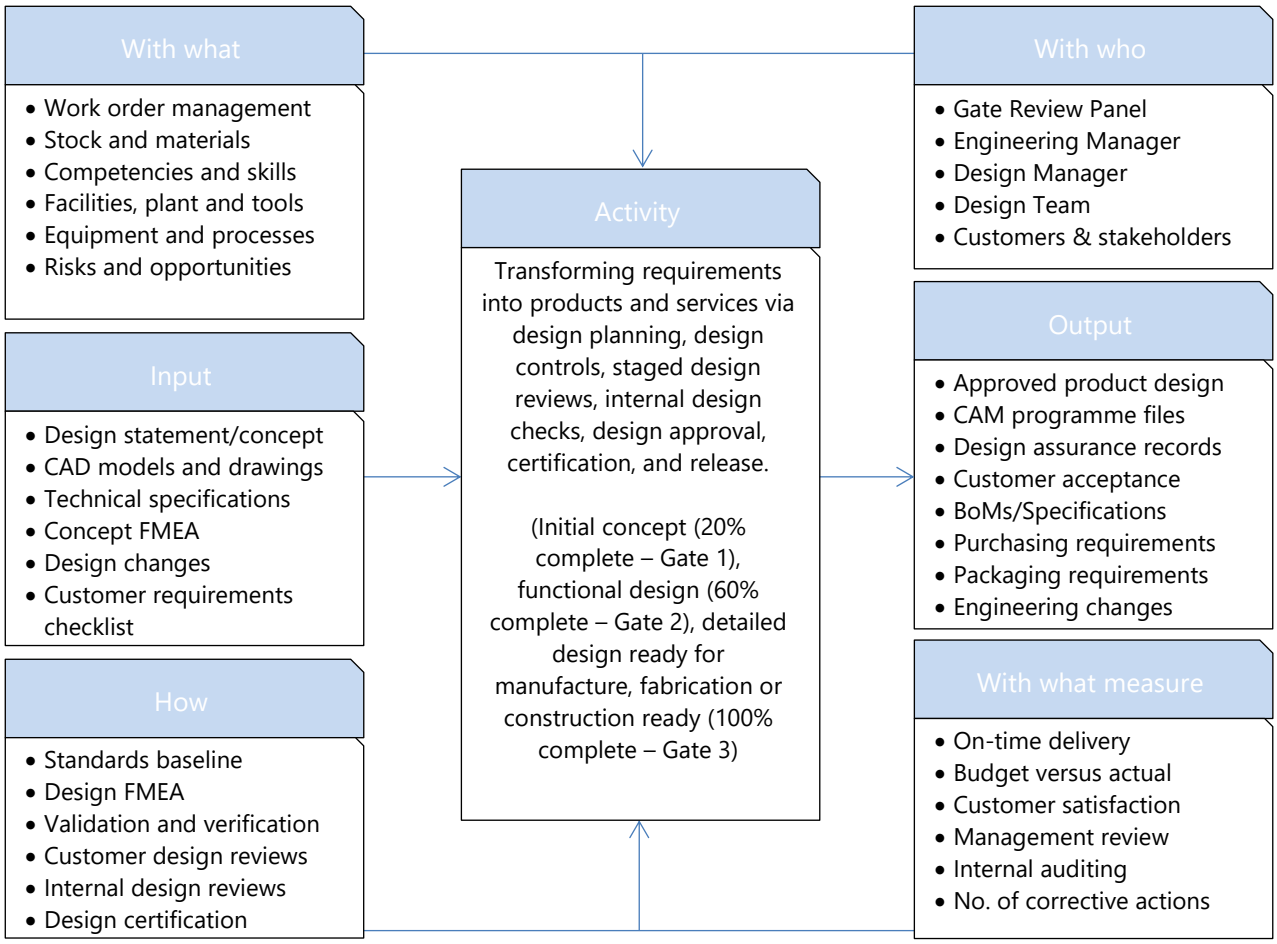
Table of Contents

1 Design Management

1.1 Introduction & Purpose

The purpose of this procedure is to ensure that all product and service design and development activities are coordinated between different organizational functions and that interfaces between stakeholder groups are defined to ensure effective communication and clear assignment of responsibility. This procedure also ensures that good quality assurance practices are used during the design process and that they are consistent with quality system requirements.

1.1.1 Process Activity Map



1.1.2 References

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2015	Quality management systems	Requirements
BS EN ISO 9004:2018	Quality management systems	Guidelines for performance improvements

1.1.3 Terms & Definitions

Term	Definition
Design and development	Transforming requirements (3.6.4) for product/service into detailed requirements
Interfacing party	A contractor, consultant, or representative responsible for design or implementation

Term	Definition
Requirements	A need or expectation that is stated, generally implied or obligatory
Verification	Confirmation, through the objective evidence (3.8.3), requirements (3.6.4) were fulfilled
Validation	Confirmation that particular requirements for a specific intended use are fulfilled
Design Input	The physical and performance requirements of a product used as a basis for design
Design Output	Documented information that defines the product
Design Review	Comprehensive examination of the design to evaluate adequacy in meeting requirements
Design Transfer	Ensures that the design is correctly translated into production specifications
Design Changes	Process for initiating, assessing the impact and approving the proposed change

1.2 Application & Scope

The scope of this procedure is to ensure that quality assurance practices are used for the design of our products and services and that they are consistent with quality system requirements. This procedure applies to the development of all products and services, including design modifications, product changes, and customer specific projects.

All design and development processes are carried out under controlled conditions where all activities are planned and documented. Designs are reviewed at appropriate stages and where applicable; verified and validated. Design outputs are verified before release for production.

Where any part of the design and development process is outsourced, the supplier will meet the requirements of this procedure and provide objective evidence that all requirements were met.

1.3 Responsibilities

Top management are responsible for;

1. Ensuring that the design management process is established and maintained;
2. Identifying customer and market demands;
3. Monitor design metrics and indicators, and undertake management reviews.

The Gate Review Panel are responsible for:

1. Meeting to review and approve designs;
2. Taking account of the views of Review Panel members;
3. Preparing and issuing review reports.

The Engineering Manager is responsible for;

1. Reducing the commercial impact of risk to acceptable levels whilst remaining within the Law;
2. Ensuring specifications for new products or services are complete;
3. Ensuring that proper design control methodologies are followed;
4. Evaluating the risks and impact against Gates criteria;
5. Managing the assured state of design changes.

The Design Manager is responsible for;

1. Planning, coordinating and expediting the development of designs;
2. Making personnel assignments and assessing the results of designs;

3. Reviewing and checking design solutions;
4. Knowing what the risks are at any point in time;
5. Presenting the design packages to the Gate Review Panel;
6. Carrying out a Designer's Risk Assessment;

The Quality Manager is required to:

1. Maintaining customer specifications and requirements, reviews changes when revised;
2. Arranging and ensuring that internal quality audits are conducted;
3. Maintaining regimes for technical quality, review, assurance, and certification of the design;
4. Maintaining systems for reporting and record keeping;
5. Reviewing the effectiveness of corrective actions taken.

The Design Team are responsible for:

1. Ensuring that all designed and developed solutions meet requirements and performance standards;
2. Designing, developing and generating all the paperwork associated with the design project;
3. Ensuring each stage of a new design or design change/development is controlled.

1.4 Design Management Process

1.4.1 Design Management Planning

The design management plan typically includes specific quality practices, assessment methodology, record-keeping, documentation requirements, resources, etc and sequence of activities relevant to a particular design or design category. The plan references applicable codes, standards, regulations and specifications. and describe the interfaces with different groups or activities that provide, or result in, an input to the design and development process.

Each design activity is planned, divided into phases, and tasks assigned to competent and skilled design personnel equipped with adequate tools and resources. Design management plans are documented and updated as the design evolves.

As required, at the commencement of a design package, the Design Manager is required to complete a Design Management Plan (DMP) which will include at a minimum:

- Confirmation of the standards baseline used for the work being undertaken and an explanation of how compliance to this baseline will be demonstrated;
- An organisation chart with defined responsibilities for all staff with direct involvement in design or with a potential impact on safety;
- Skills matrix to define the competence of individuals with 'prepare', 'check' and 'approval' duties;
- Scope definition and interface identification including key issues and operational requirements;
- Projected output, timelines, milestones, and defined deliverables;
- Stated processes and procedures to ensure acceptable quality assurance will be demonstrated and records maintained (specifically the formal Assurance Gates);
- Processes and procedures to be used to ensure compliance with the engineering safety management;
- The design review process, both single (SDR) and multi-design consultant (IDR) reviews and stakeholder intervention, prior to the Assurance Gate Reviews at 20%, 60% & 100% design completion stages;
- Explanation of how compliance with input requirements will be demonstrated.